



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

OCT 29 1998

Food and Drug Administration
Washington, DC 20204

7 3 7 7 '98 NOV -4 P 1 :45

Ms. De Lois L. Shelton
Regulatory Compliance
Weider Nutrition International, Inc.
2002 South 5070 West
Salt Lake City, Utah 84104-4836

Dear Ms. Shelton:

This is in response to your letter of October 20, 1998 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Weider Nutrition International, Inc. is making the following statements, among others, for the products:

Schiff Acidophilus Lactobacillus Product #10529, #10530, and #10531
Schiff Acidophilus with Goat Milk product #10500, #10502, and #10504

“Necessary for Successful Implantation and Competitive Exclusion of
Pathogenic Bacteria”

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for these products suggest that they are intended to treat, prevent, mitigate, or cure diseases, namely, various digestive disorders caused by pathogenic microorganisms. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Your submission also indicates that, for the product **Beta Glucan**, you are making the claims “...may be the agent responsible for the cholesterol-lowering effects of oat bran...” and “normalizing cholesterol levels.”

These statements are not statements of nutritional support subject to 21 U.S.C. 343(r)(6), but are health claims subject to 21 U.S.C. 343(r)(1)(B). FDA has authorized a health claim on the relationship between soluble fiber from certain foods (such as beta glucan or oat bran) and risk of coronary heart disease and the ability of soluble fiber to reduce blood cholesterol (see 21 CFR 101.81). A dietary supplement that meets the eligibility and

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message requirements set forth in this regulation may bear a claim for the relationship between soluble fiber from oat bran and risk of coronary heart disease. A health claim on the label or in the labeling of a food or dietary supplement that is not in accordance with the requirements in 21 CFR 101.81 would misbrand the food or dietary supplement under 21 U.S.C. 343(r)(1)(B). Moreover, failure to make a claim in accordance with the requirements in 21 CFR 101.81 subjects the product to regulation as a drug under 21 U.S.C. 321(g)(1)(B) because the product is intended to treat, cure, prevent, or mitigate a disease, coronary heart disease and/or hypercholesterolemia.

Please contact us if we may be of further assistance.

Sincerely,

Lynn A. Larsen, Ph.D.
Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, Denver District Office, Office of Compliance, HFR-SW340

cc:

HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO)
HFS-456 (file)
HFS-450 (r/f, file)
HFD-310 (BWilliams)
HFD-314 (Aronson)
HFS-600 (Reynolds)
HFS-605 (Bowers)
GCF-1 (Nickerson, Dorsey)
init:GCF-1:DDorsey:10/27/98
f/t:HFS-456:rjm:10/28/98:docname:61925.adv:disc32

NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA

In compliance with Section 6 of the Dietary Supplement Health Education Act (DSHEA) and Rule 21 C.F.R. 101.93, this Notification is filed on behalf of the following manufacturer of **Schiff® Acidophilus Lactobacillus Product #10529, #10530, #10531** bearing the statements set out below:

Weider Nutrition International, Inc.
2002 South 5070 West
Salt Lake City, Utah 84104

The text of each structure-function claim for **20,000 CFU Acidophilus Lactobacillus (*L. acidophilus, thermophilus, bulgaricus*)** is as follows:

(Statement 1) Digestive Tract Balance

(Statement 2) A source of beneficial microorganisms which help maintain a normal balance of healthy flora (bacteria) in the lower intestines for optimal functioning of the digestive tract.

(Statement 3) New Schiff® Acidophilus nutritionally supports friendly flora for optimal health and balance in the digestive system. Even the best health care can sometimes fall short of the mark, upsetting the body's natural flora balance. Acidophilus are beneficial microorganisms which help maintain a normal balance of healthy flora (bacteria) for optimal functioning of your digestive system.

- A. Utilizes Carbohydrates to Survive and Flourish
- B. Only Carbohydrate in the Woman's Reproductive System, Essential for Women's Health
- C. Necessary for Successful Implantation and Competitive Exclusion of Pathogenic Bacteria
- D. Fosters Environment Conductive to Helpful Bacteria
- E. Necessary for Survival in the Small Intestine
- F. Required for Passage Through the Stomach

Also see docket 97S-0163

I, Luke R. Bucci, Ph.D., CCN, CNS, Vice President of Research at Weider Nutrition International, Inc. am authorized to certify this Notification of behalf of the Company. I certify that the information presented and contained in this Notification is complete and accurate and that the Office of Regulatory Affairs at Weider Nutrition International, Inc. has substantiation that each statement is truthful and not misleading.

DATED this 1st day of June, 199 9.

WEIDER NUTRITION INTERNATIONAL, INC.

BY:

DR. LUKE R. BUCCI

Vice President of Research

NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA

In compliance with Section 6 of the Dietary Supplement Health Education Act (DSHEA) and Rule 21 C.F.R. 101.93, this Notification is filed on behalf of the following manufacturer of **Schiff® Acidophilus with Goat Milk Product #10500, #10502, #10504** bearing the statements set out below:

Weider Nutrition International., Inc.
2002 South 5070 West
Salt Lake City, Utah 84104

The text of each structure-function claim for **20,000 CFU Acidophilus Lactobacillus (*L. acidophilus, thermophilus, bulgaricus*)** is as follows:

(Statement 1) Digestive Tract Balance

(Statement 2) A source of beneficial microorganisms which help maintain a normal balance of healthy flora (bacteria) in the lower intestines for optimal functioning of the digestive tract.

(Statement 3) New **Schiff® Acidophilus** nutritionally supports friendly flora for optimal health and balance in the digestive system. Even the best health care can sometimes fall short of the mark, upsetting the body's natural flora balance. Acidophilus are beneficial microorganisms which help maintain a normal balance of healthy flora (bacteria) for optimal functioning of your digestive system.

- A. Utilizes Carbohydrates to Survive and Flourish
- B. Only Carbohydrate in the Woman's Reproductive System, Essential for Women's Health
- C. Necessary for Successful Implantation and Competitive Exclusion of Pathogenic Bacteria
- D. Fosters Environment Conductive to Helpful Bacteria
- E. Necessary for Survival in the Small Intestine
- F. Required for Passage Through the Stomach

Also see docket 975-0163

I, Luke R. Bucci, Ph.D., CCN, CNS, Vice President of Research at Weider Nutrition International, Inc. am authorized to certify this Notification of behalf of the Company. I certify that the information presented and contained in this Notification is complete and accurate and that the Office of Regulatory Affairs at Weider Nutrition International, Inc. has substantiation that each statement is truthful and not misleading.

DATED this 19th day of October, 199 8.

WEIDER NUTRITION INTERNATIONAL, INC.

BY:

DR. LUKE R. BUCCI

DR. LUKE R. BUCCI

Vice President of Research

NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA

In compliance with Section 6 of the Dietary Supplement Health Education Act (DSHEA) and Rule 21 C.F.R. 101.93, this Notification is filed on behalf of the following manufacturer of **Schiff® Phytocharged™ Oat Beta Glucan Product #12806** bearing the statements set out below:

Weider Nutrition International., Inc.
2002 South 5070 West
Salt Lake City, Utah 84104

The text of each structure-function claim for **750mg Beta Glucan** is as follows:

- (Statement 1) Provides nutritional support for heart and circulatory health.
- (Statement 2) **Beta Glucan** is a soluble fiber that can be isolated from cereals such as oats. Many studies confirm that beta-glucan may be the agent responsible for the cholesterol-lowering effects of oat bran through its interaction with cholesterol in the intestinal tract thus normalizing cholesterol levels. Schiff® uses Nurture® beta-Glucan which is extracted from Tibor oats in a patented process that promotes stability and preserves the grain's beneficial properties.
- (Statement 3)

I, Luke R. Bucci, Ph.D., CCN, CNS, Vice President of Research at Weider Nutrition International., Inc. am authorized to certify this Notification of behalf of the Company. I certify that the information presented and contained in this Notification is complete and accurate and that the Office of Regulatory Affairs at Weider Nutrition International, Inc. has substantiation that each statement is truthful and not misleading.

DATED this 19th day of October, 1998.

WEIDER NUTRITION INTERNATIONAL, INC.

BY:

LSR Bucci

DR. LUKE R. BUCCI

Vice President of Research

ALSO see docket 97S-0163